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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,757	03/29/2004	Hsiang Wang	39524.9800	2850

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EXAMINER	
MCCORMICK EWOLDT, SUSAN BETH	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,757	WANG ET AL.	
	Examiner	Art Unit	
	Susan B. McCormick-Ewoldt	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *February 25, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on June 10, 2005 is acknowledged.

Claims 22-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 10, 2005.

Claims Pending

Claims 1-21 will be examined on the merits.

Claim Objections

Duplicate Claims Warning

Applicant is advised that should claims 1-6 be found allowable, claims 8-13 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 15 and 20 the parentheses are indefinite in the limitation of the claim because it is not clear if it is a required limitation.

Claim 15, line 3 the term "anhydrousor" appears to be misspelled. Clarification is needed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-8, 16-17 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuok *et al.* (US 6,790,464 B2).

Kuok *et al.* (US 6,790,464 B2) teach a composition that contains *Fructus cnidii* and *Semen cuscutae* which can be extracted with an alcohol extract such as ethanol. The composition can be incorporated into any means of administration such as liquid, tablet powder, capsule or by injection (column 7, lines 6, 16-17; column 10, lines 28-31, 53-55, 59-61; column 16, 66-67; column 17, lines 1, 24-35; claim 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13, 16-18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuok *et al.* (US 6,790,464 B2).

Kuok *et al.* (US 6,790,464 B2) disclose a composition for the treatment of prostate disorders and prostatic carcinoma which contains *Fructus cnidii* and *Semen cuscutae* which can be extracted with an alcohol extract such as ethanol. The composition can include various additional ingredients such as minerals (i.e. calcium) and can be incorporated into any means of administration such as liquid, tablet powder, capsule or by injection (column 7, lines 6, 16-17; column 9, lines 58-60; column 10, lines 28-31, 53-55, 59-61; column 16, 66-67; column 17, lines 1, 24-35).

The reference does not teach using the ingredients in the amounts claimed or formulating the composition in all of the claimed forms. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re* Aller, 220 F2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). See MPEP § 2144.05 part II. Variations of components in pharmaceutical compositions and in pharmaceutical forms were well known in the art. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration and pharmaceutical forms are an art-recognized result-effective variables that would have been routinely determined and optimized in the pharmaceutical art. Further, one of ordinary skill in the art would have been motivated to have modified the proportions of active ingredients in the composition and the dosage form in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment. Such variations in amounts of pharmaceutically active ingredients and dosage form are considered merely optimization of result-effective variables, conventional practice in the art of pharmacology.

Claims 14-15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuok *et al.* (US 6,790,464 B2) as applied to claims 1-13, 16-18 and 21 above, and further in view of Baron (US 2004/0071789).

Kuok *et al.* (US 6,790,464 B2) disclose a composition for the treatment of prostate disorders and prostatic carcinoma which contains *Fructus cnidii* and *Semen cuscutae* which can be extracted with an alcohol extract such as ethanol. The composition can include various additional ingredients such as minerals (i.e. calcium) and can be incorporated into any means of administration such as liquid, tablet powder, capsule or by injection (column 7, lines 6, 16-17; column 9, lines 58-60; column 10, lines 28-31, 53-55, 59-61; column 16, 66-67; column 17, lines 1, 24-35). Kuok *et al.* does not disclose the specific calcium-containing substances or vitamin D_3.

Baron (US 2004/0071789) discloses a composition of administering calcium (i.e. calcium carbonate or calcium phosphate) and vitamin D can be added to the composition to reduce the risk of prostate carcinoma ([0010], [0014], [0068] and [0071]).

These references show that it was well known in the art at the time of the invention to use the claimed ingredients in compositions that treat prostate disorders and prostatic carcinoma. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re* Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re* Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re* Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in compositions to treat prostate disorders and prostatic carcinoma, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating compositions to treat prostate disorders and prostatic carcinoma. Therefore, the artisan would have been motivated to combine the claimed ingredients into a single composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re* Sussman, 1943 C.D. 518; *In re* Huellmantel 139 USPQ 496; *In re* Crockett 126 USPQ 186.

Summary

No claim is allowed.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

sbme

Susan D. Coe
6-27-05
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PRIMARY EXAMINER